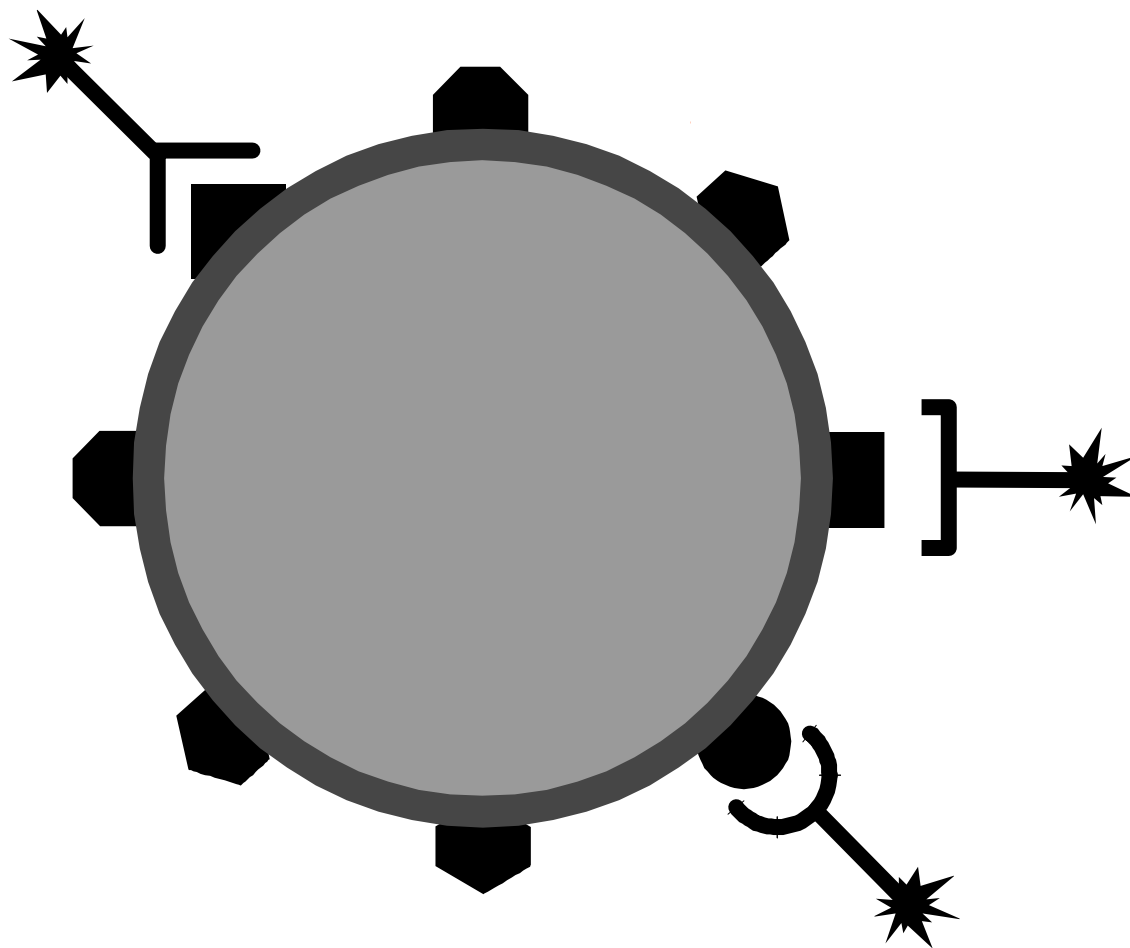


Results of the 1999 T-Lymphocyte Immunophenotyping Questionnaire Survey Mailed to Laboratories Participating in the Model Performance Evaluation Program



T-Lymphocyte Immunophenotyping by Multi-Platform and Single-Platform Methods



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention



Report of results for a 1999 T-lymphocyte Immunophenotyping (TLI) laboratory
questionnaire survey mailed to laboratories participating in the Model Performance
Evaluation Program, Centers for Disease Control and Prevention (CDC).

Production of this report was coordinated in CDC by:

Public Health Practice Program Office Edward L. Baker, M.D., M.P.H.
Director

Division of Laboratory Systems Robert Martin, Dr.P.H.
Director

Laboratory Practice Assessment Branch Thomas L. Hearn, Ph.D.
Acting Chief

The material in this report was developed and prepared by:

Model Performance Evaluation Program (MPEP) William O. Schalla, M.S.
Chief

MPEP TLI Performance Evaluation G. David Cross, M.S.
MPEP TLI Project Coordinator

Use of trade names and commercial sources is for identification only and does not
constitute endorsement by the Public Health Service or the U.S. Department of Health and
Human Services.

Information about this report should be addressed to the Model Performance Evaluation
Program by calling (770) 488-8098 or (770) 488-8091.

Introductory Comments

The aggregate results from a mailed questionnaire survey conducted by the Model Performance Evaluation Program (MPEP) in May 1999 of laboratories in the United States performing T-lymphocyte immunophenotyping (TLI) are presented in the following figures and tables. Of the 321 laboratories receiving this survey, 273 (85.0%) reported results. The "N" numbers appearing in each figure or table reflect the total number of laboratories responding to the specific question. For multiple response questions, the total number of responses may exceed the actual number of laboratories responding to that specific question.

The map located on page 2 reflects the enrollment in the MPEP TLI program at the time this survey was mailed, and may not reflect the current enrollment in this program.

The primary classification of all the laboratories in the MPEP TLI program at the time the survey was mailed is shown in the top figure on page 4. The primary classification of only those laboratories responding to the survey is shown in the bottom figure on the same page. The further classifications of the responding laboratories are shown in the responses for questions 5(a)-5(e).

Please note that wording for questions 6 and 7, regarding the education and certification requirements of the laboratory director and supervisor, reflect current regulatory requirements related to the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), as published in CFR 42, Part 493.

The term "single-platform method" was defined to be those methods for obtaining absolute CD4⁺ T-cell counts using a single-instrument, for example, FACSCount or Imagn 2000, or laboratory test, for example, TRAx CD4 or Zymmune assay. The term "multi-platform method" was defined to be those methods that derive absolute CD4⁺ T-cell counts by using the percent CD4⁺ T-cells obtained from a flow cytometer in combination with the absolute lymphocyte count obtained from a hematology instrument.

Responses to question 8 reflect the amount of experience necessary to perform either single-platform or multi-platform methods.

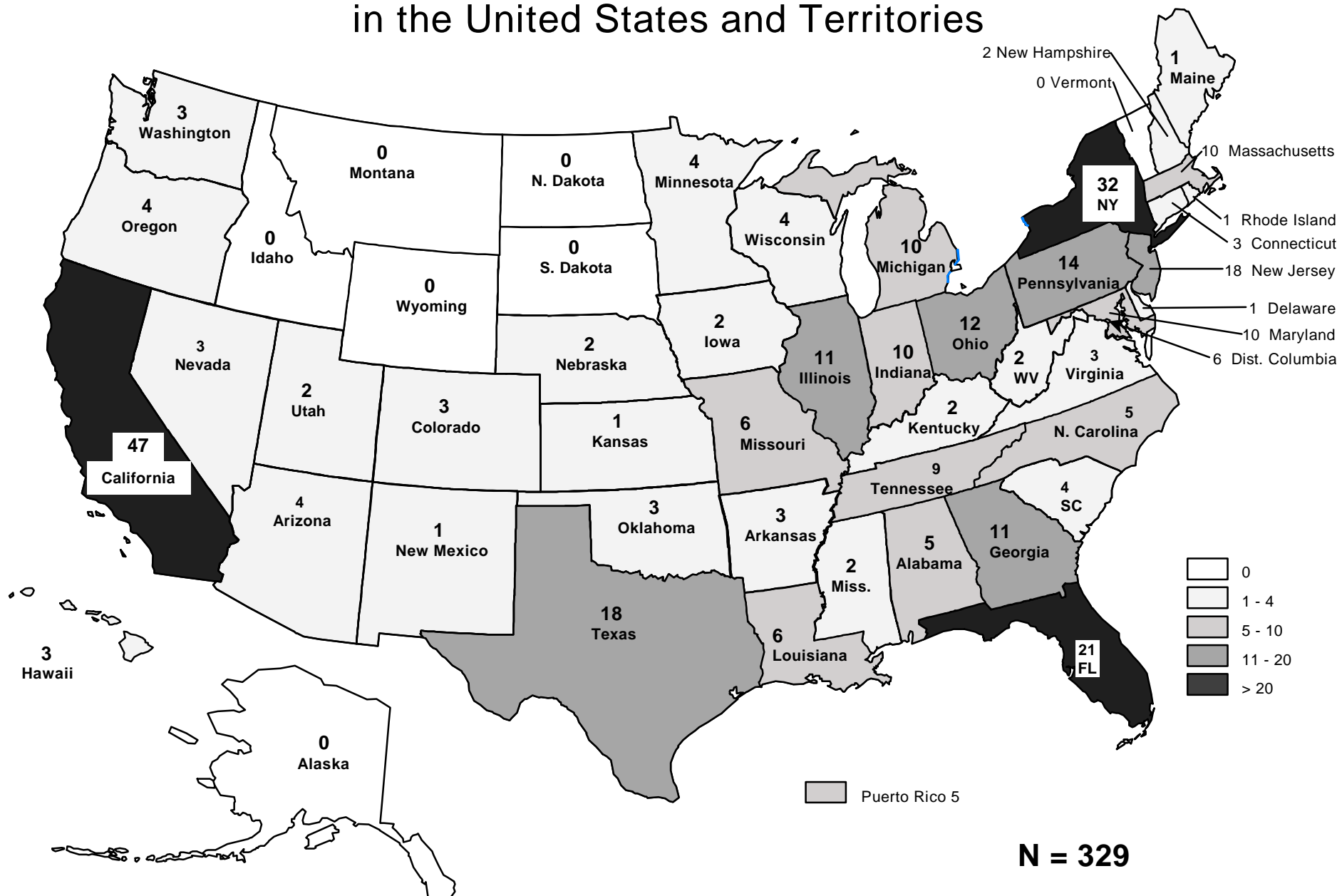
Question 27 requested information regarding the monoclonal antibody manufacturer associated with reagents for each of the cell marker combinations routinely used for performing TLI. The first two pages of results for this question, pages 37-38, show the reagents used for single-color, two-color, three-color, and four-color tests. A summary of monoclonal antibody reagents used by participant laboratories is shown on page 39. Pages 40 through 43 show the monoclonal antibody reagent panels used by the participant laboratories.

Question 44 requested information regarding the price charged for TLI performed by single-platform or multi-platform methods.

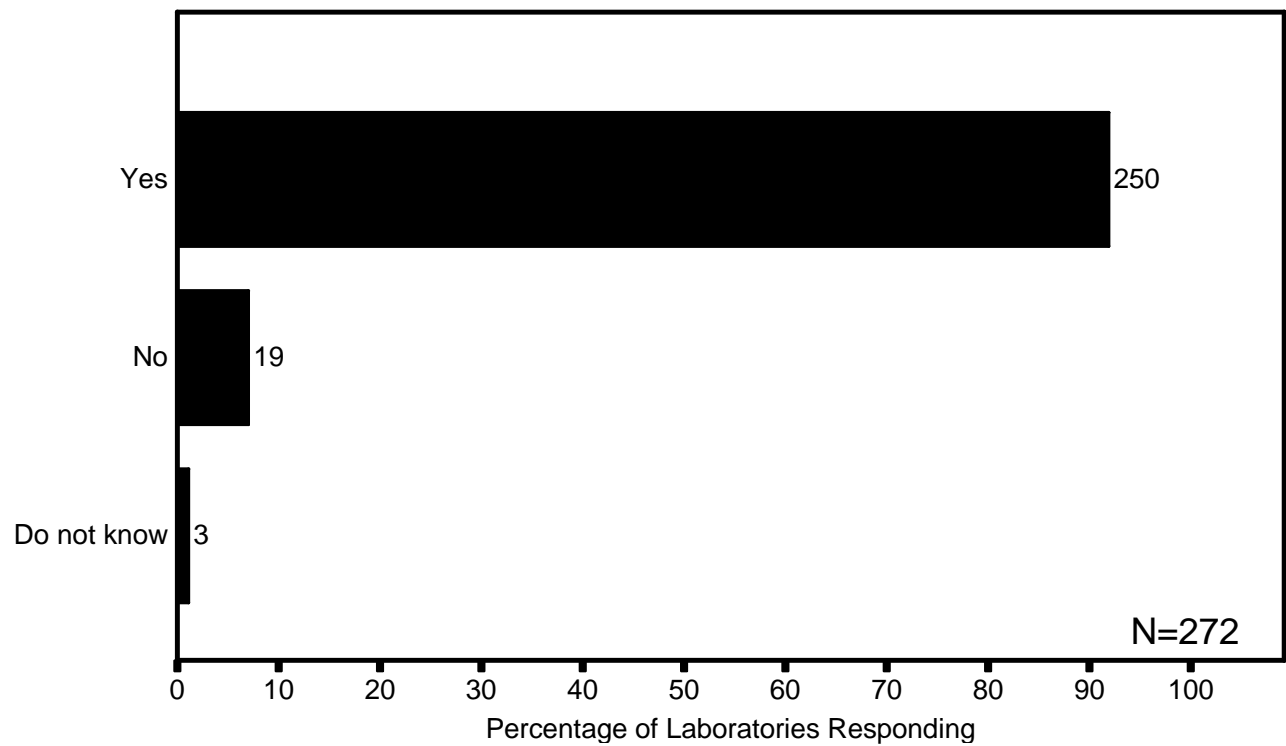
Responses to Question 45 reflect the external proficiency testing programs in which participant laboratories are enrolled.

Questions 46 and 47 requested information regarding the surrogate-marker tests and the other tests for HIV infection which are performed by participant laboratories.

Number of MPEP TLI Laboratories in the United States and Territories

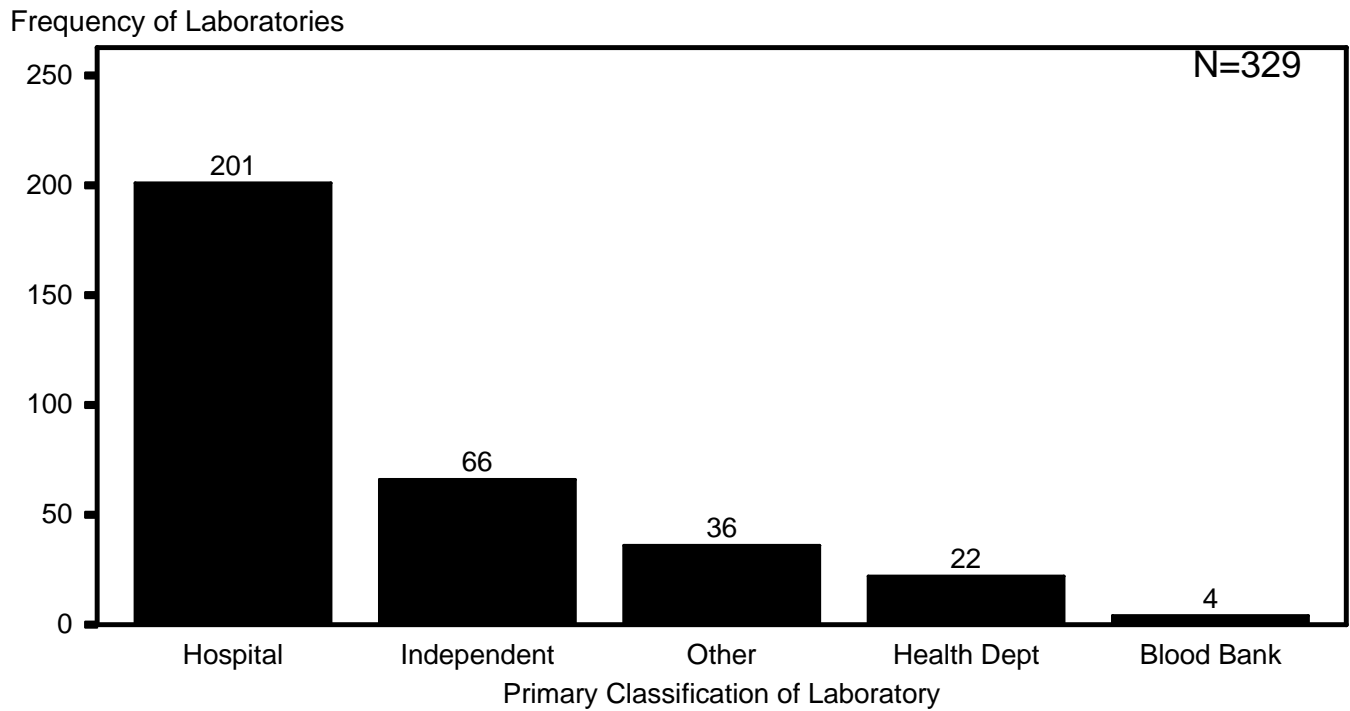


4. In the last year, has your laboratory performed TLI for HIV-infected patients?

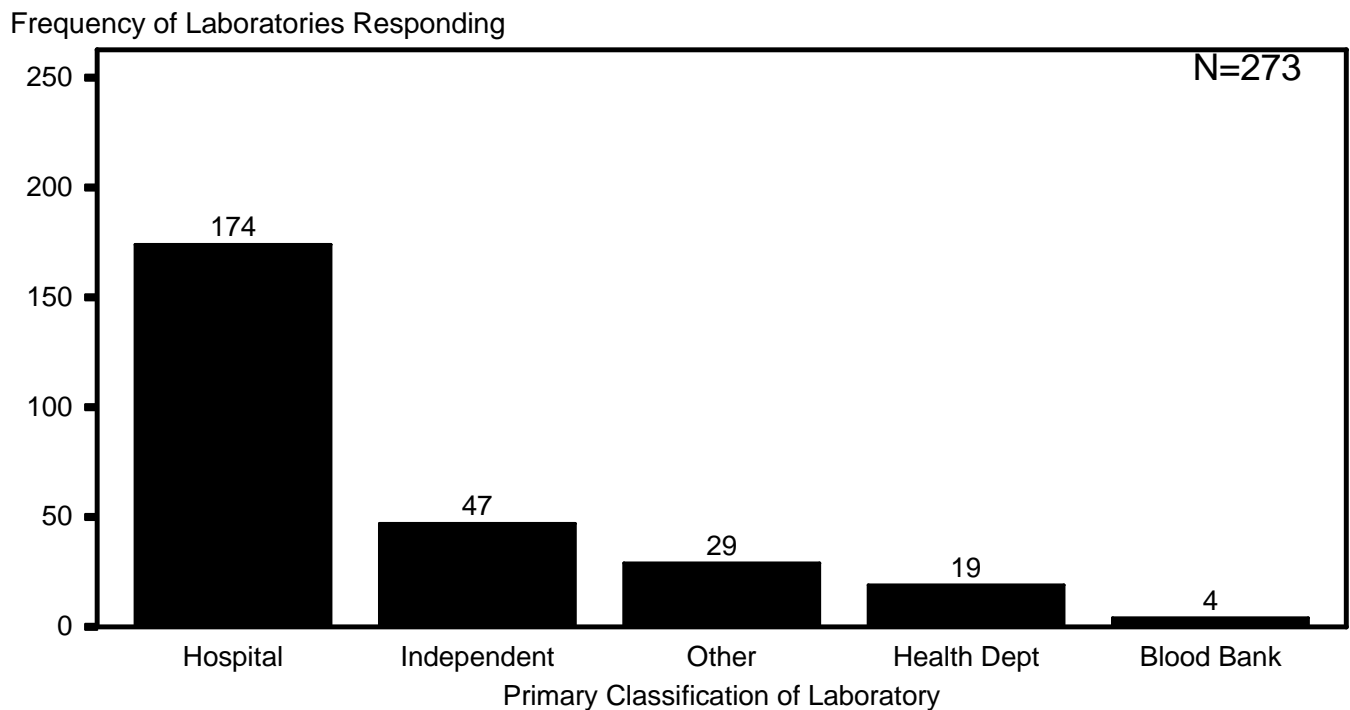


Primary Classification of MPEP Laboratories in Regard to TLI Testing

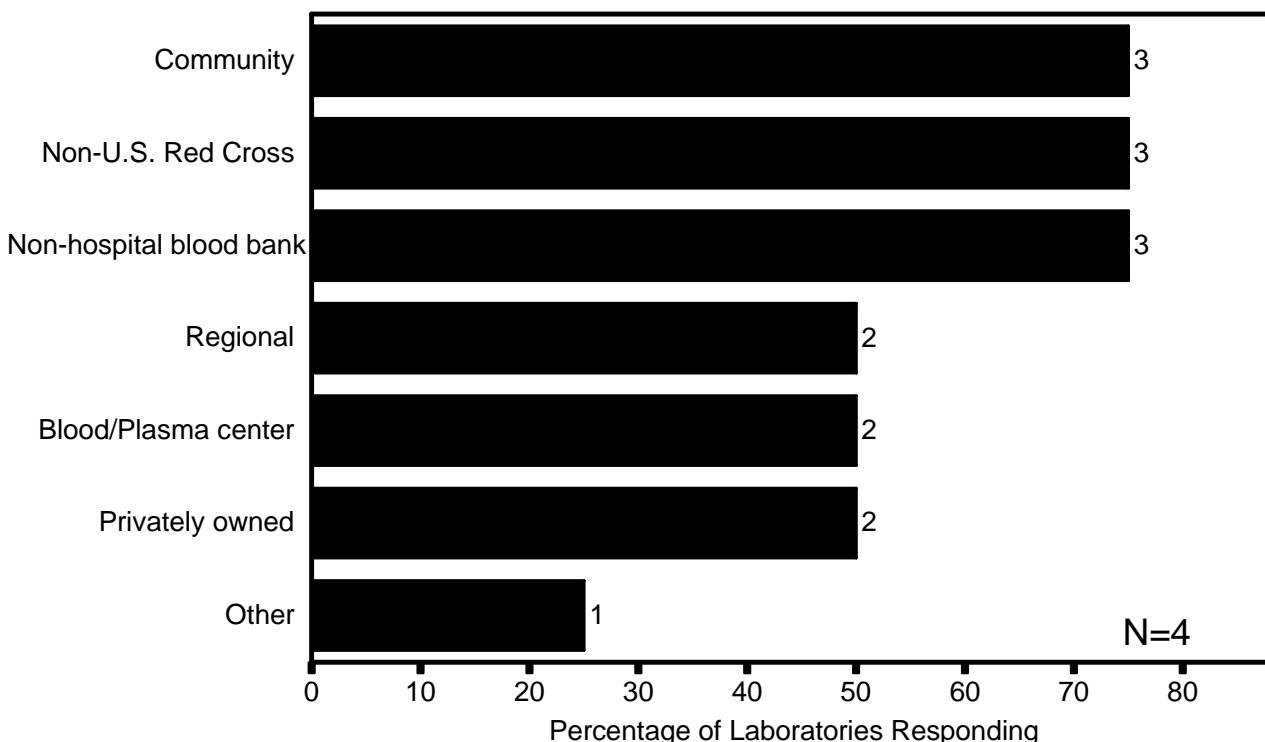
Total Number of Laboratories in TLI Program



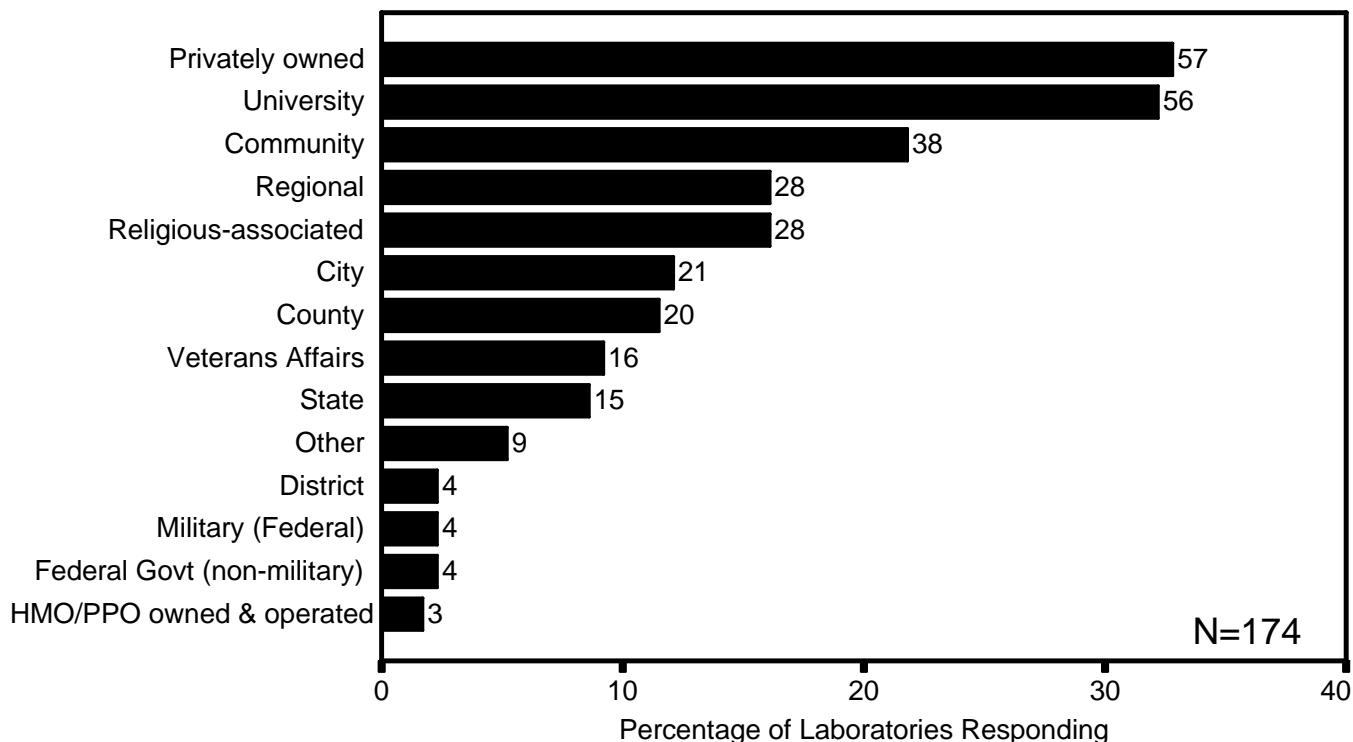
Laboratories Responding to Questionnaire Survey



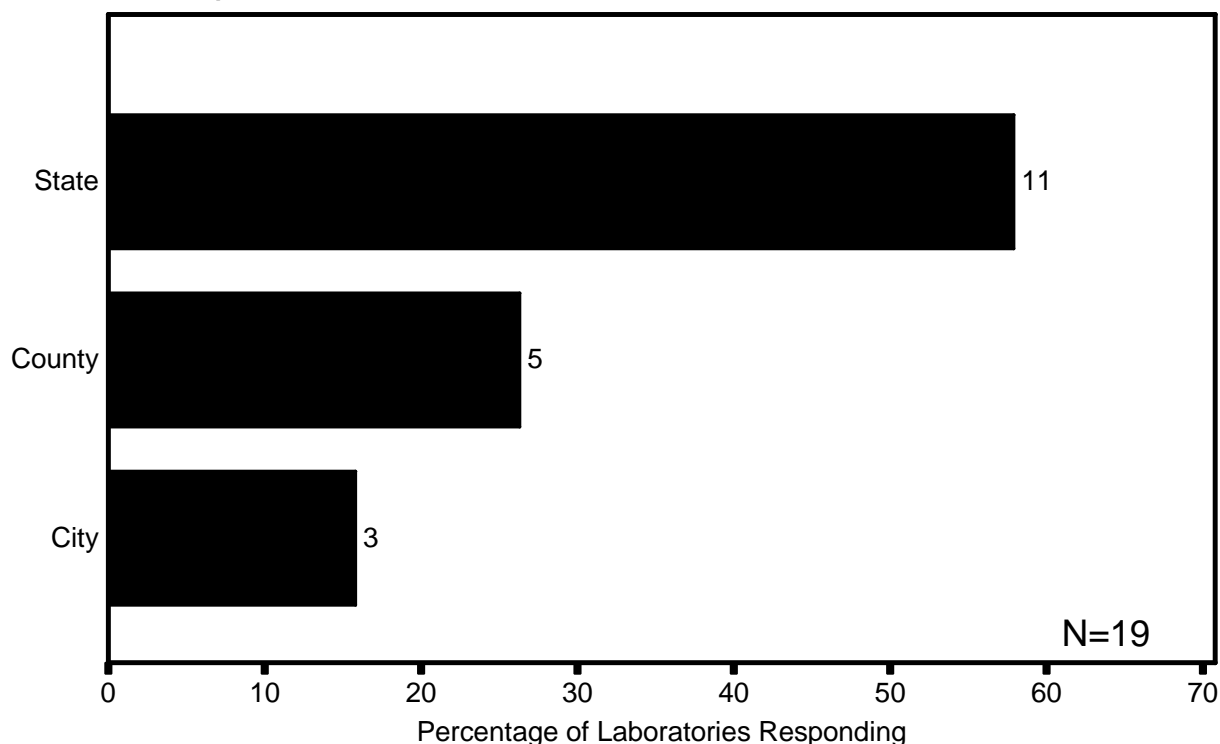
5.(a) If the laboratory type shown on your mailing label (located on page one) is BLOOD BANK, please further describe your TLI testing laboratory (Check all that apply within your Blood Bank laboratory classification.):



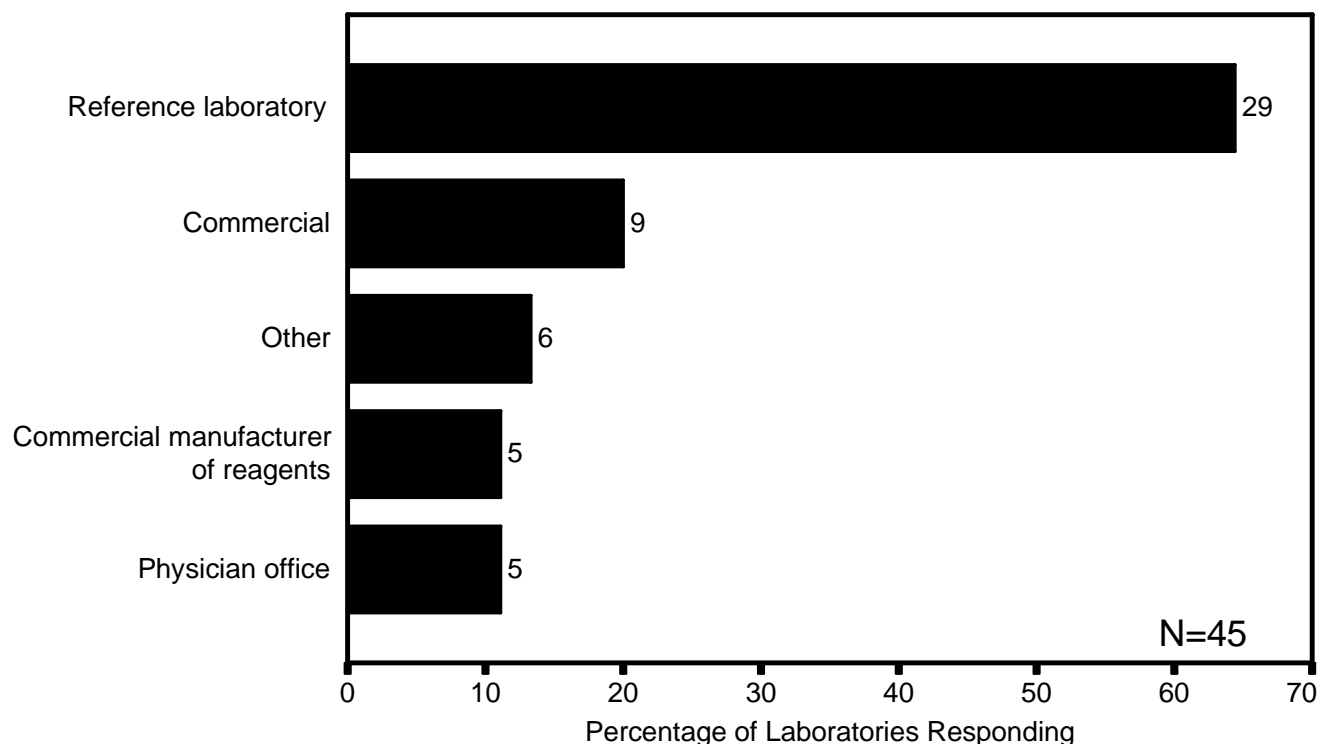
5.(b) If the laboratory type shown on your mailing label (located on page one) is HOSPITAL, please further describe your TLI testing laboratory (Check all that apply within your Hospital laboratory classification.):



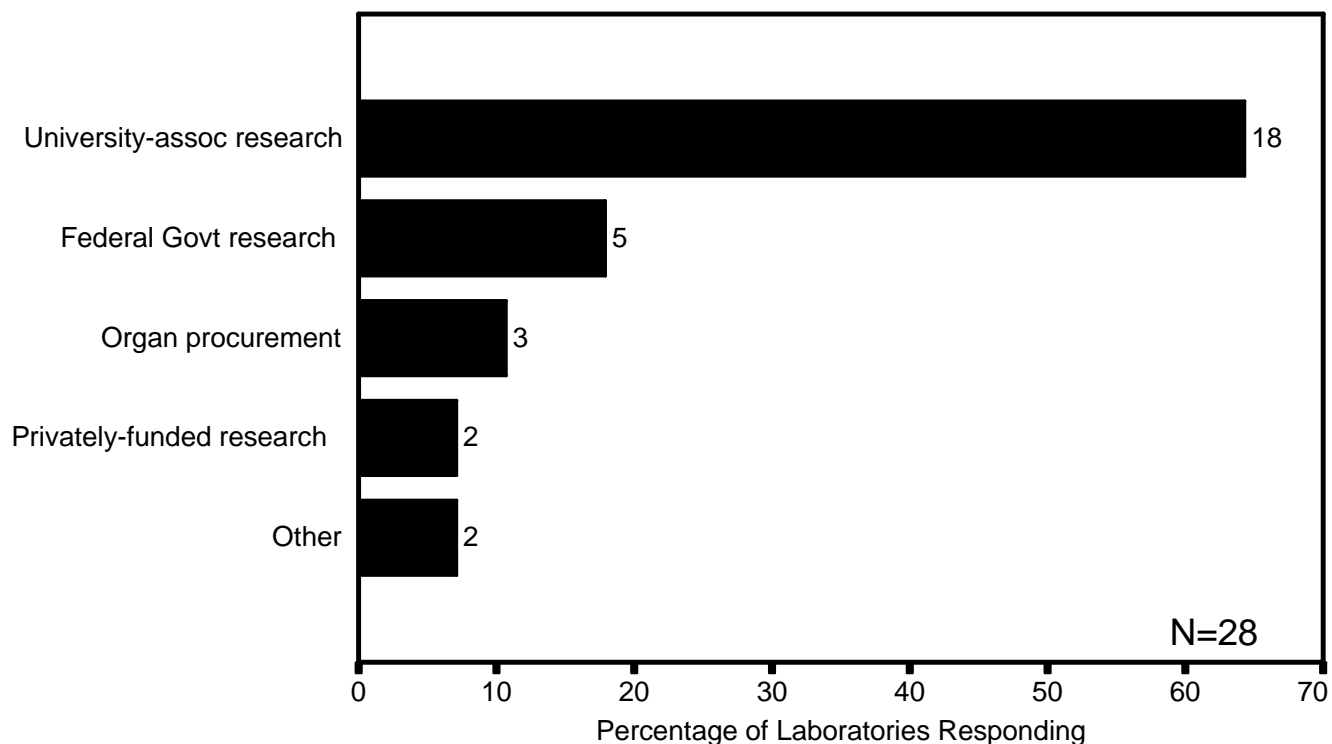
5.(c) If the laboratory type shown on your mailing label (located on page one) is HEALTH DEPARTMENT, please further describe your TLI testing laboratory (Check all that apply within your Health Department laboratory classification.):



5.(d) If the laboratory type shown on your mailing label (located on page one) is INDEPENDENT, please further describe your TLI testing laboratory (Check all that apply within your Independent laboratory classification.):

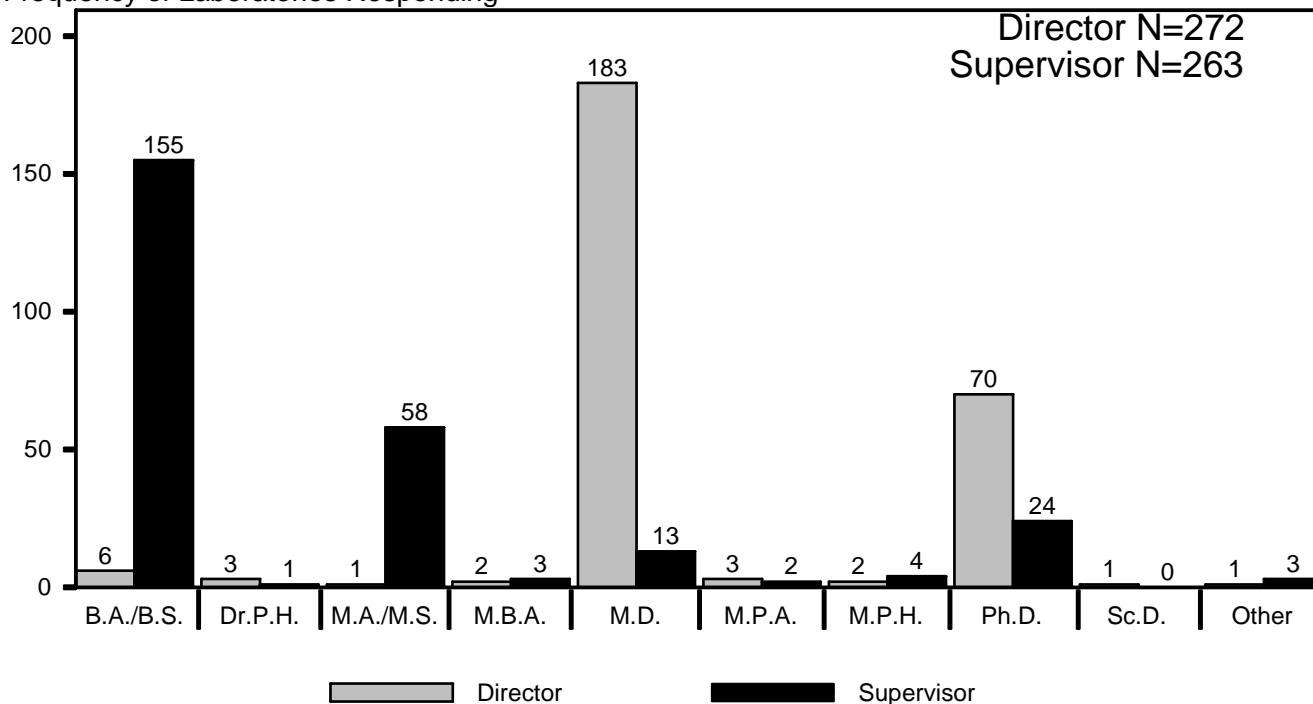


5.(e) If the laboratory type shown on your mailing label (located on page one) is OTHER, please further describe your TLI testing laboratory (Check all that apply within your Other laboratory classification.):



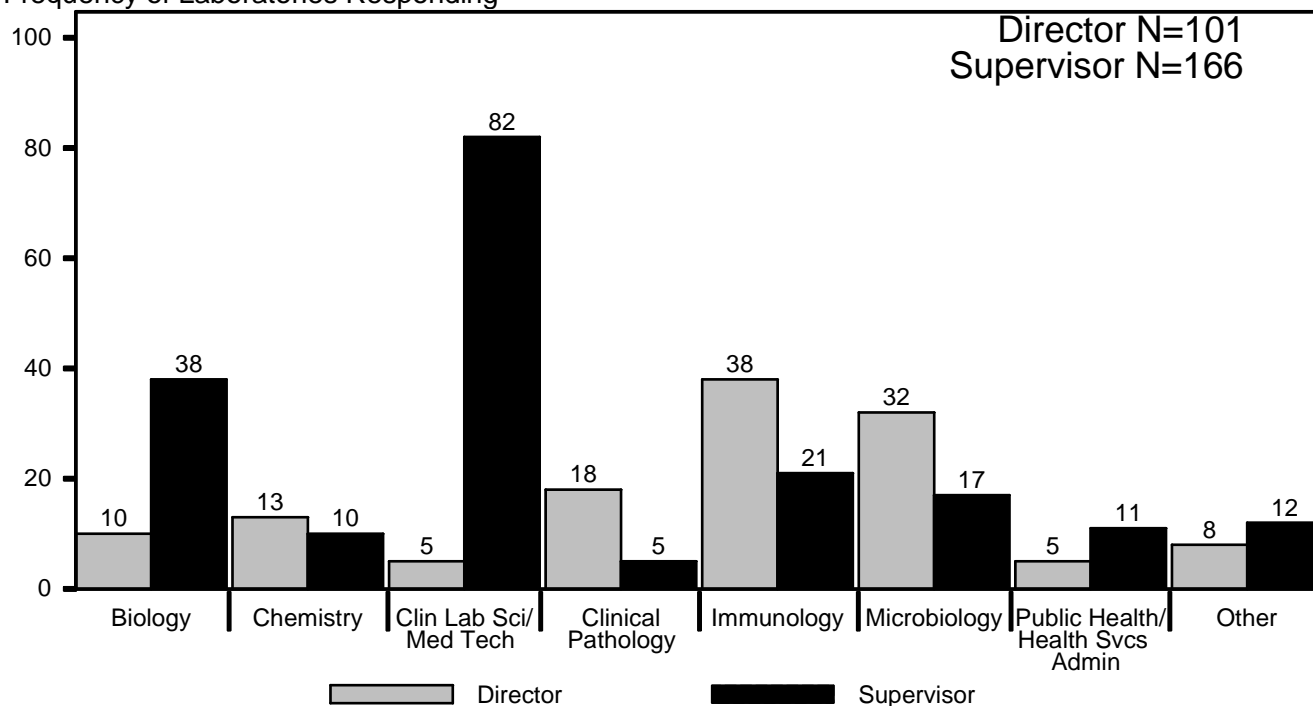
6.(a) Please choose from the list below the highest academic degree that has been awarded to your Laboratory Director and Laboratory Supervisor (Choose only one degree for each person.):

Frequency of Laboratories Responding

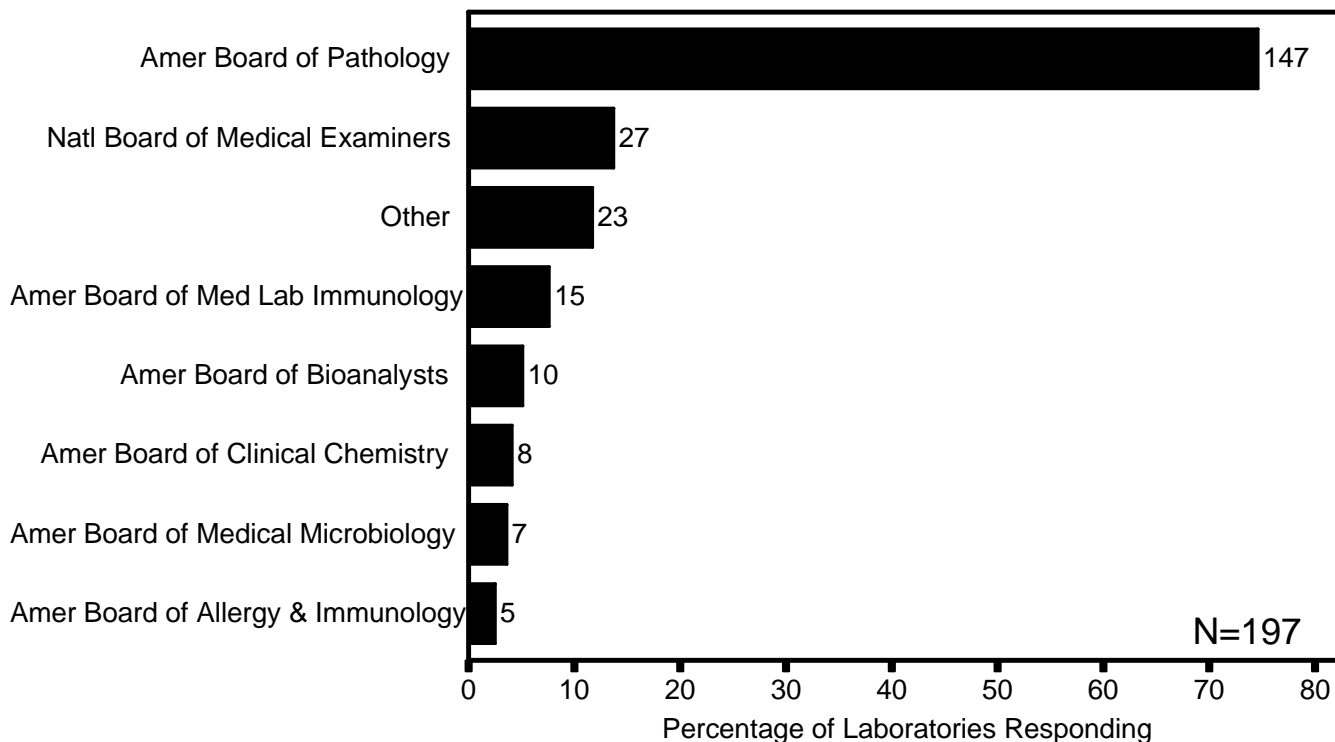


6.(b) If your Laboratory Director or Laboratory Supervisor has a degree other than M.D. or D.O., please indicate the academic discipline in which the degree was awarded (Check all that apply.):

Frequency of Laboratories Responding



6.(c) What board certifications have been awarded to your Laboratory Director? (Check all that apply.)



6.(d) Please indicate the years of experience your Laboratory Director has in directing or supervising laboratory testing (Round off to the nearest whole number.):

Frequency of Laboratories Responding

